1. **Purpose**

The quantitative determination of D-Dimer in human citrated plasma reported in D-Dimer Equivalent Units (FEU).

1. **Principle**
	1. The specific degradation of fibrin (i.e., fibrinolysis) is the reactive mechanism responding to the formation of fibrin. Plasmin is the fibrinolytic enzyme derived from inactive plasminogen. Plasminogen is converted into plasmin by plasminogen activators. The main plasminogen activators are tissue plasminogen activator (tPA) and pro-urokinase which is activated into urokinase (UK) by, among others, the contact system of coagulation. In the bloodstream, plasmin is rapidly and specifically neutralized by alpha 2 – antiplasmin, thereby restricting its D-Dimerolytic activity and localizes the fibrinolysis on the fibrin clot. On the fibrin clot plasmin degrades fibrin into various products, (i.e., D-Dimers). Antibodies specific for these products, which do not recognize D-Dimer, have been developed. The presence of these various fibrin degradation products, among which D-Dimer is the terminal product, is the proof that the fibrinolytic system is in action in response to coagulation activation.
	2. Clinical applications for this test are as follows: Disseminated Intravascular Coagulation (DIC), negative predictor for the diagnosis of a thrombotic episode (i.e., DVT, PE), efficacy of treatment for a thrombotic episode and screen for possible re-occurrence (MI), and screen for other activation states of coagulation (i.e., post-operative, cancer, cirrhosis).
	3. The principle of the test is as follows. When a beam of monochromatic light is allowed to transverse a suspension of microlatex particles to which specific antibodies have been attached by covalent bonding and if the wavelength of the light is much greater than the diameter of the latex particles, the light is only slightly absorbed. In the presence of the antigen being tested for, the antibody-coated latex particles agglutinate to form aggregates of a diameter greater than the wavelength of the light, more of the latter is absorbed. This increase in light absorption is a function of the antigen level present in the test sample.
2. **SPECIMEN**
	1. Collection Tubes
		1. Becton Dickinson (B‑D) #366415 blue top tube containing 0.5 ml buffered 3.2% sodium citrate in a sterile, silicone‑coated tube.
			1. Approximate draw 4.5 ml blood ±10% to achieve a 9:1 blood to anticoagulant ratio.
		2. Becton Dickinson (B‑D) #36308 pediatric blue top tube containing 0.2 ml buffered 3.2% sodium citrate in a sterile, silicone coated tube.
			1. Approximate draw 2.7 ml ±10% to achieve a 9:1 blood to anticoagulant ratio.
	2. Establishing Proper Tube Fill
		1. A minimum and maximum draw tube demographic is kept at the coagulation station against which each specimen is to be compared. Any specimen not falling within acceptable range is to be rejected (see **HEM10-001**,Rejection of Hematology Specimens Procedure).
			1. "Short draw" tubes provide insufficient blood for the amount of anticoagulant and lead to prolonged results.
			2. Overfilled tubes are unacceptable because insufficient anti-coagulation may occur, especially in severely anemic patients.
	3. Specimen handling
		1. Stability
			1. Coagulation testing is optimally performed within two (2) hours, but no longer than twenty-four hours, following collection. Once a specimen is uncapped, stability is (4) hours following collection.
		2. Centrifugation
			1. Centrifuge for 7 minutes at 5,500 rpm OR 10 minutes at 3,500 rpm (within 30 minutes of collection).This speed or centrifuge will yield platelet poor plasma.
			2. Centrifuge STATs for 6 minutes at 4500 rpm using the EBA centrifuge. This speed or centrifuge will yield platelet poor plasma.
		3. Removal of Plasma
			1. Using a plastic transfer pipette, transfer the plasma into a plastic tube and cap. Transcribe the patient's name, medical record number or DOB, accession number, and date unto the plastic tube. Place tube in the freezer in Blood Bank. This is to be followed for samples not processed within 24 hours of collection. Samples may be frozen for 2 weeks; do rapid thaw and process within 1 hour.
		4. Checking for Hemolysis and visible clots
			1. Check plasma for visible clots and hemolysis; the presence of visibly pink plasma indicates RBC destruction, which may have occurred in vivo prior to or during or after filling the collection tube. (The presence of hemolysis strongly suggests the possibility of in vitro clots.) Append "HEM" to the result (hemolyzed).
		5. Sample Storage
			1. Room Temperature
				1. Centrifuged samples can be left up to 24 hours at room temperature.
		6. Freezing
			1. If the sample must be frozen and tested later, quick freezing of the plasma in small aliquots at ‑70oC is desirable to prevent formation of ice particles.
				1. **NOTE**: Frozen plasma should be rapidly thawed at 37oC before testing. (Factor VII and factor XI activities may increase with storage when frozen.)
3. **Equipment and Materials**
	1. Equipment
		1. MLA or Volumetric pipette
		2. Centrifuge
	2. Materials
		1. Tips for volumetric pipette
		2. Cuvettes
		3. Printer paper
		4. Waste container
		5. Specimen Cup
4. **Instrumentation**
	1. Identification

|  |  |  |  |
| --- | --- | --- | --- |
| **Facility** | **Name** | **Serial #** | **“Live” Date** |
| **EMCP** | Compact Max 1 | SN5071531 | 3-15-2016 |
| Compact Max 2 | SN5071537 | 3-15-2016 |
| **EMC-EP** | Compact Max 3 | SN5061483 | 3-15-2016 |
| Start 4 | B932 | 3-15-2016 |

### STANDARDS AND CONTROLS

* 1. A new range is established for each new lot of control material by repetitive analysis on both instruments for one month, during which the manufacturer’s range is used.
1. STA® Liatest® Control N+P **(Cat. No. 00526)**
	* 1. Reconstitution
			1. Reconstitute each vial of control with exactly 1mL of distilled water.
			2. Allow the material to stand at room temperature for 30 minutes.
			3. Swirl each vial gently before use.
		2. Storage and Stability
			1. Unreconstituted vials are stable until the expiration date listed on the box label when stored at 2-8 oC.
			2. Once reconstituted both levels of controls are stable for 8 hours and is to be kept on board the analyzer.
		3. Loading on the analyzer
			1. Click Products then Loading Products or click the  icon to request the product drawer.
			2. Scan the barcode on the reagent bottle and press Enter **⮠**
			3. Select  and click confirm to close the drawer.
		4. Running and Reviewing QC
			1. Qc can be ordered from the Quality Control Menu
			2. All controls are monitored automatically by the Compact Max.
				1. Any controls outside the ± 2SD range will result in audible and visual alarms.
			3. Results can be reviewed in the individual QC files.
			4. All controls must be resulted on form HEM40-012/HEM40-013/HEM40-014/HEM40-015/HEM40-016 Form A Daily Qc on Stago and in the Lab Information System.
			5. Control results are automatically filed on the STA Compact Max QC file
			6. All results for a 24 hour period will be converted to a “mean” value on the first run after midnight.
				1. This mean is used in the statistical data and is plotted on the Levi- Jennings chart as a daily mean.
			7. Print all the QC data points prior to the first run after midnight.
				1. Prior to midnight when the analyzer is not running any test s click the  icon or select Quality Controls and the Windows Methodologies List appears.
				2. Double click the **D-DI** test and click the QC Tables icon 
				3. Click the  icon.

Printout dialogue box will appear. Select print then click confirm.

* + - * 1. Click the  icon to return to the QC Graph.
				2. Click **Next Level** and repeat process for other levels.
1. **Reagents**
	1. All new reagent package inserts are reviewed by the Supervisor, Lead Technologist, or designee and compared with the current lot numbers to ensure no changes have been made. The current package insert is signed and dated with the date the new reagents are put into use.
	2. Reagent 1: Tris Buffer: Ready to use. Allow the reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then, place a STA® mini Reducer **(Cat. No. 00797)** and the perforated cap on the vial perforated plastic cap on the vial. Click **Products,** then **Loading Products** or click the  icon to open the product drawer. Scan the barcode on the reagent bottle. Press **Enter** ⮠ , and then place the reagent into the product drawer on the STA Compact Max®. Select  and click **Confirm** to close the drawer. Stability after opening: 15 days on the STA Compact Max® Analyzer.
	3. Reagent 2: Latex: Ready to use. Suspension of microlatex particles coated with two different mouse monoclonal anti-human D-Dimer antibodies (8D2 and 2.1.16) then stabilized with bovine albumin. Allow reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then, place a STA® mini Reducer **(Cat. No. 00797)** and the perforated cap on the vial perforated plastic cap on the vial. . Click **Products,** then **Loading Products** or click the  icon to open the product drawer. Scan the barcode on the reagent bottle. Press **Enter** **⮠** , and then place the reagent into the product drawer on the STA Compact Max®. Select  and click **Confirm** to close the drawer.
	4. Stability after opening: 15 days on the STA Compact Max® Analyzer.
	5. Reagent 2: STA**®** - Owren-Koller buffer (Cat. No. 00360): Ready to use buffer. Used by the STA Compact Max® to perform dilutions of controls and patients’ plasmas.
		1. STA® DESORB U [Cat. No. 0975]: is a decontaminating solution (contains KOH < 1%) for use with the STA**®** line of instruments.
			1. Install a new STA**®** - maxi reducer (REF 00801) and the perforated cap on a freshly opened bottle before loading in the reagent drawer.
		2. STA**®** - Cleaner Solution [Cat. No. 0973]: is a washing aqueous solution used on the STA**®** line of instruments. Sufficient STA**®** - Cleaner Solution must be loaded to operate the analyzer.
	6. Load Reagents
		1. Click Products, then loading products or click the  icon to open the product drawer.
		2. Scan the barcode on the reagent bottle and press Enter **⮠**
			1. Place the reagent into a stirring position in the product drawer
		3. Select  and click confirm to close the drawer
	7. Parts information and Physical Requirements
		1. Refer to instrument reference manual
	8. Routine Maintenance
		1. Refer to The Stago operators manual regarding all daily, weekly, and as needed maintenance.
			1. Record all maintenance on Stago Compact Maintenance form HEM40-012/HEM40-013/HEM40-014/HEM40-015/HEM40-016 Form B Stago Maintenance.
	9. Error Messages
		1. If there is not enough reagent(s) to run the test(s), the deficient reagent(s) and the amount of reagent necessary to complete the testing will appear in red.
		2. This deficiency will BLOCK the SAMPLE PIPETTING and the icon will appear on the bottom of the screen. When you receive this error you need add the necessary reagent(s).
			1. Respond to the error “New Tests are Delayed- Reactivate?” With N or NO.
			2. Add required reagents to the drawer and reactivate test(s).
	10. Emptying of waste
		1. Liquid Waste
			1. The Stago does not contain Sodium Azide and can be discarded in a dirty sink. The instrument utilizes emptied rinse containers as its liquid waste chamber. When replacing the rinse bottle also remove the waste container and dump the liquid waste down the drain of a dirty sink. The rinse bottle being replaced is now used to collect future liquid waste.
		2. Cuvettes
			1. When the cuvette waste is full remove the bag from inside the analyzer and dispose of in the sharps container. Replace the yellow biohazard liner of the cuvette waste container.
2. **Procedure**
	1. **Running Quality Control**
		1. Click theicon or click Quality Controls and the Methodologies list appears.
		2. Select the check box for D Dimer and click the  icon.
		3. Type the access code and click Confirm.
		4. A yellow triangle  is displayed to the right of the methodology showing the selected Quality Control is running.
	2. **Running Patient Samples.**
		1. Click Patient Analyses
		2. Click loading samples or the  icon.
		3. After the drawer opens, identify the type of specimen by clicking the box
			1. micro-sample
			2. Stat (urgent) by clicking the box.
		4. Identify the sample by scanning the bar-code or manually entering the ID using the keyboard.
		5. Place the specimen into the drawer.
			1. In AUTO MODE, the STA CompactMax® will automatically order the test(s) selected in the AUTO MODE profile.
			2. In MANUAL MODE, the operator must order the test(s) from the Selection menu, or from the Recorded Profile(s). Double click each methodology or Profile, click **Confirm**.
		6. As soon as the sample drawer closes, the ANALYSIS STATUS screen will appear.
			1. If there is not enough reagent(s) to run the test(s), the deficient reagent(s) and the amount of reagent necessary to complete the testing will appear in red.
			2. This deficiency will BLOCK the SAMPLE PIPETTING and the icon will appear on the bottom of the screen. When you receive this error you need add the necessary reagent(s).
				1. Respond to the error “New Tests are Delayed- Reactivate?” with N or NO.
		7. Add required reagents to the drawer and reactivate test(s).
			1. All patient results are displayed on the **TEST PANEL** screen and automatically print out and transmit if selected on the **SYSTEM** menu.
			2. For results in question that need operator intervention, cursor to the identification number in the **TEST PANEL** screen and double click.
				1. This will display the **PATIENT REPORT FORM** screen for the specific sample. Follow the options on the bottom of the screen (i.e. Confirm, Re-run, Delete, Add test). Click the  icon to save the changes.
				2. Click the icon to return to the **TEST PANEL** screen.
		8. **Running Quality Control**
			1. Click theicon or click Quality Controls and the Methodologies list appears.
			2. Select the check box for D Dimer and click the  icon.
			3. Type the access code and click Confirm.
			4. A yellow triangle  is displayed to the right of the methodology showing the selected Quality Control is running.
		9. **Running Patient Samples.**
			1. Click Patient Analyses
			2. Click loading samples or the  icon.
			3. After the drawer opens, identify the type of specimen by clicking the box
				1. micro-sample
				2. Stat (urgent) by clicking the box.
			4. Identify the sample by scanning the bar-code or manually entering the ID using the keyboard.
			5. Place the specimen into the drawer.
				1. In AUTO MODE, the STA CompactMax® will automatically order the test(s) selected in the AUTO MODE profile.
				2. In MANUAL MODE, the operator must order the test(s) from the Selection menu, or from the Recorded Profile(s). Double click each methodology or Profile, click **Confirm**.
			6. As soon as the sample drawer closes, the ANALYSIS STATUS screen will appear.
				1. If there is not enough reagent(s) to run the test(s), the deficient reagent(s) and the amount of reagent necessary to complete the testing will appear in red.
				2. This deficiency will BLOCK the SAMPLE PIPETTING and the icon will appear on the bottom of the screen. When you receive this error you need add the necessary reagent(s).

Respond to the error “New Tests are Delayed- Reactivate?” with N or NO.

Add required reagents to the drawer and reactivate test(s).

* + - 1. All patient results are displayed on the **TEST PANEL** screen and automatically print out and transmit if selected on the **SYSTEM** menu.
			2. For results in question that need operator intervention, cursor to the identification number in the **TEST PANEL** screen and double click.
				1. This will display the **PATIENT REPORT FORM** screen for the specific sample. Follow the options on the bottom of the screen (i.e. Confirm, Re-run, Delete, Add test). Click the  icon to save the changes.
				2. Click the icon to return to the **TEST PANEL** screen.
1. **CALCULATIONS**
	1. Instrument
		1. The STA Compact Max® automatically plots the results in delta OD off of a standard curve and converts the results to *u*g/ml.
		2. The assay uses the sample undiluted. If the result is greater than the range of results on the calibration curve (AMR) 0.27 - 4.00 *u*g/ml, the STA**®** System automatically dilutes this sample to a 1:5 dilution to expand the reportable range (CRR) to 20 *u*g/ml. The STA Compact Max® automatically corrects the result for the dilution change. The 1:5 dilution is the highest dilution that can be added to this test. If the auto redilute feature is necessary the results are displayed on the Screen in Blue numerals, instead of the normal Black numerals.
	2. In Cerner
		1. The Stago reports O.D in *u*g/ml, a calculation is applied in Cerner to convert the units to ng/mL.
			1. Stago result (*u*g/ml) X 10^3=Reported Result in ng/mL
2. **QUALITY ASSURANCE**
	1. Tolerance Limits of Controls
		1. Acceptable limits for STAGO are calculated monthly via Stago Clarity peer comparison program.
		2. All control ranges are monitored by the STAGO. If any controls are outside the SD range, the STAGO will audibly and visually alarm the operator by FAILING.
		3. Otherwise, the results can be found in the QC files. Control results are automatically filed in the STAG QC LOG.
		4. QC is also monitored in Cerner via ARE. Data points must be entered into the LIS, using ARE function. If a data point fails criteria, QC must be rerun and corrective action documented on form **HEM40-003/HEM40-004/HEM40-005/HEM40-007/HEM40-009/HEM40-010 Form B**.
	2. Out of Tolerance Controls
		1. When control time values fall outside of set limits:
			1. Repeat to verify.
			2. Recheck all instrument operations and volume of reagents onboard and ensure sufficient volume of sample, and confirm expiration time and date.
			3. Open and reconstitute a new vial of control material, making sure the Protocol water and not saline is used.
			4. If step #3 is still out of tolerance, notify supervisor and call Biomedical Engineering.
			5. Write comment in Action Log (form **HEM40-003/HEM40-004/HEM40-005/HEM40-007/HEM40-009/HEM40-010 Form B**).
	3. Tolerance Limits For Acceptable Performance ‑‑ Patient Samples
	4. Any D-Dimer <.22 ug/mL FEU or 220 ng/ml FEU should be checked for clots then repeated for confirmation.
	5. Tolerance Limits of Temperature Controlled Areas
		1. Reagent Cooling System
		2. Maintain reagents at 25oC or lower. Instruments will Auto Stop when temperatures of controlled areas are out of range.
	6. Frequency of Assay
		1. Each Shift:
		2. The Normal and Abnormal Control must be assayed at least every 8 hours when patient testing is performed.
	7. Quality Control Program
		1. New Lot of Controls
			1. When a new lot of control is put in use utilize the assayed range over twenty runs to establish and or confirm assayed range.
		2. Failed QC
			1. Failed QC on the STAGO will cause a FAILED flag on the printout alerting staff of a problem which should result in a repeat of the failed control. If failed QC is acceptable on the basis of the Cerner range, still repeat failed control(s) on the analyzer. If controls continue to fail alert Lead Tech or Supervisor.
		3. Controls in Cerner
			1. Controls are released into LIS QC files for Westgard rules. All QC is released the same as a patient result in Cerner and **requires** technical review prior to release.
	8. INSTRUMENT CORRELATION
		1. The four STAGO instruments are correlated semiannually.
			1. Three patient samples are to be processed for correlation on each instrument and recorded on form **HEM40-003/HEM40-004/HEM40-005/HEM40-007/HEM40-009/HEM40-010 Form C** Semi-Annual Coagulation Instrument Correlations.
				1. D-Dimers are to correlate +/-0.67 ug/mL.
	9. Verification of platelet poor plasma
		1. The actual platelet concentration of the normally spun plasma used for coagulation testing is counted semiannually or when centrifuge is changed to confirm that it is platelet-poor.
			1. Obtain plasma from spun blue top tube.
			2. Run plasma on the Hematology analyzer.
			3. Print out and record on form **HEM40-003/HEM40-004/HEM40-005/HEM40-007/HEM40-009/HEM40-010 Form D** Centrifuge Platelet Concentration Correlation.
			4. The platelet count of this platelet poor plasma must be less than 10,000
			5. Notify supervisor if outside acceptable limits and discontinue use of centrifuge.
3. **REFERENCE RANGE.**
	1. Less than 0.50 ug/ml FEU on the Stago and 500ng/ml FEU.
4. **REPORTING RESULTS**
	1. The results for the Liatest® D-Dimer are reported out to the nearest hundredth decimal point. (Example: 0.41 ug/ml). When the calculation is applied in Cerner result will be reported as 410ng/mL.
5. BACK‑UP INSTRUMENTATION AND/OR METHODOLOGY
6. EMC has two Stago instruments, which serve as backups for each other.
7. EP has one Stago Compact Max instrument and One Start 4, , which serve as backups for each other
8. In the event of a total system shutdown or instrumentation failure in which ECMP Stago Compacts are out of service, specimens must be transported to another facility (i.e. ECM-EP or Montgomery).
9. In the event of a total system shutdown or instrumentation failure in which ECM-EP Stago analyzers are out of service specimens must be transported to another facility (i.e. ECMP or Montgomery).
10. **CALIBRATION**
	1. The kit reagents are pre-calibrated: this calibration is identical for all reagents of each lot.
	2. Entering the data for the calibration curve: When the operator scans a new lot of Liatest D-Dimer reagent, the STA Compact Max® will request the operator to scan the barcode printed on the barcode insert across the barcode reader.
	3. The calibration curve will be validated for the lot being used when the two Liatest D-Dimer control levels have been run. If the validation controls are outside the assayed range, the STA Compact Max® will not run patient d-dimer samples until the controls are validated.
	4. View calibration curve on STA Compact Max® on the screen: In the **TEST** **PANEL** screen select **CALIBRATION** or click the icon. In the CALIBRATION screen double click D-DI. The curve will appear on STA Compact Max ® screen
	5. Print calibration curve: While viewing the curve on the STA Compact Max® screen, click the icon. The STA Compact Max® cannot print a calibration curve while the analyzer is running.
	6. Calibration Verification
		1. All calibrated test must be re-calibrated every six months. Since a pre-calibrated test cannot be calibrated every six months, Calibration Verification must be performed in lieu of the calibration.
		2. Run commercial linearity product, reference standard, or patient samples with known results. The calibration verification must consist of at least 3 points located on the calibration curve.
		3. Samples can be frozen in advance.
		4. Verify that the raw data of the dependent tests fall on the original curve used to define the AMR.
		5. Enter the data into the appropriate template to verify that the calibration curve is valid. Criteria for acceptance: refer to specific template.
		6. Sample criteria for calibration verification is as follows:
			1. Plasma sample should have a level between 3.0 – 3.8 ug/ml FEU
			2. Build dependent tests for D-Dimer.
				1. DDI2: 1:2 with dilution factor 2.0
				2. DDI 4: 1:4 with dilution factor 4.0
				3. DDI8: 1:8 with dilution factor 8.0
				4. DDI 15: 1:15 with dilution factor 15.0
				5. Perform 1:1 (repeat undiluted), 1:2, 1:4, 1:8, and 1:15 D-Dimer tests on a high specimen (3.0 – 3.8 ug/mL FEU).
				6. Evaluate the calculated theoretical value (target value) for each dilution versus the actual assay result for that dilution.
				7. Criteria for acceptance: The results should be equivalent to the target values

for samples <1.0 ug/mL FEU + 0.15 ug/Ml

for samples >1.0 -4.0 ug/mL FEU + 0.50 ug/mL

* + - * 1. The data will verify the calibration verification
				2. Two levels of Quality Control validate the accuracy of the calibration each time the assay is performed.
1. **ANALYTICAL MEASUREMENT RANGE (AMR) & CLINICAL REPORTABLE RANGE (CRR)**
	1. All tests which are calibrated and directly measure the concentration or activity of an analyte by employing enzyme immunoassay (EIA), immunoturbidity and chromogenic methods must have a defined Analytical Measurement Range (AMR) and Clinical Reportable Range (CRR). This does not apply to clotting assays.
	2. The Analytical Measurement Range (AMR) is the range of analyte values that a method can directly measure on a specimen without any dilution, concentration or pretreatment not part of the usual assay process. The AMR validation is the process of confirming that the assay system will recover the concentration or activity of the analyte over the AMR.
		1. The calibration curve defines the AMR and satisfies the requirement of the AMR verification if the matrix of the calibrator is appropriate and employs at least 3 points that fall in the low, mid and high range of the AMR.
		2. This must be verified prior to reporting patient results and every six (6) months thereafter, or at lot change, whichever comes first.
	3. The Clinical Reportable Range (CRR) is the measured range after the specimen is diluted, concentrated or pre-treated in order to expand the direct AMR.
		1. The laboratory should define the maximum dilution that falls within the AMR.
		2. The diluted sample raw data must fall within the AMR of the original curve.
		3. If the dilution fails to bring the raw data within the AMR, the result may be reported as “greater than” (>) the established upper CRR limit or “less than” (<) the established lower CRR limit. For most tests, the lower CRR limit is equal to the lower AMR limit.
2. **TEST AMR/CRR LIMITS**
	1. The package insert states that the Analytical Measurement Range (AMR) of the reagent on the STA**®** System instrument is 0.27 - 4.00 *u*g/ml without dilution.
	2. The Clinical Reportable Range on the STA Compact Max® instrument is expanded to 20 *u*g/ml with the addition of an alternate dilution defined in the Methodologies as a 1:5 auto re-dilution. The STA Compact Max® automatically corrects the result for the dilution change. The 1:5 dilution is the highest dilution that can be added to this test.
3. **NEGATIVE PREDICTIVE VALUE**
	1. Each laboratory should use the manufacturer’s cut-off value or threshold for the D-Dimer to be used in the diagnostic algorithm for the aid in diagnosis or exclusion of Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE).   This value has been verified by:
		1. Peer reviewed literature.
		2. Confirmed during validation studies
4. **LIMITATIONS**
	1. Cloudy plasmas may lead to an under-estimation of the D-Dimer level. Ensure that the absorbance value at 540 nm of the plasma diluted 1:6 with STA**®** - Owren-Koller buffer is < 0.35.
	2. An over-estimation of D-Dimer level may be seen in the following conditions; FDP concentrations greater than 15 *u*g/ml, the presence of rheumatoid factor at a level greater than 50 IU/ml, and the presence of anti-bovine albumin and/or anti-mouse antibodies in certain subjects
	3. The STA**®** Liatest**®** D-Dimer is insensitive to the following substances: hemoglobin (up to 2 g/l); conjugated bilirubin (up to 290 mg/l); unconjugated bilirubin (up to 200 mg/l); unfractionated heparin (up to 2 IU/ml0), and LMWH (up to 2 anti-Xa IU/ml).
5. **NOTES**
	1. The detection threshold of the STA**®** Liatest**®** D-Dimer on the STACompact Max® is 0.27 *u*g/ml FEU. The printout limits are pre-set at 0.27 – 4.00 *u*g/ml FEU. When a dependent test is set-up to extend the reportable range of the main test, the print out limit should be extended to 20.00 *u*g/ml FEU.

**REFERENCES**

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3. STA**® -** Owren-Koller Buffer (Cat. No. 00360)Buffer Solution for CoagulationTesting. Package insert 23070 06 – April 2012.
4. STA - Desorb U (Cat. No. 0975) Decontamination solution for STA**®** analyzer systems. Package insert #26265 – revised June 2011.
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*For additional information, please refer to the manufacturer’s package insert.*

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**Approval signatures:**

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## *Review History*

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| **Date****Reviewed** | **Reviewed By** | **Revisions** |
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